Metal Composition

Promus ELITE™ Everolimus-Eluting Platinum Chromium Coronary Stent System

The Promus ELITE stent implant is made from Platinum Chromium alloy and nominally consists of the following elements (with additional trace elements):

Promus ELITE Stent	Elemental Composition by Weight
Platinum	33%
Chromium	18%
Iron	37%
Nickel	9%
Molybdenum	2.63%

The delivery catheter is comprised of a proximal PTFE coated stainless steel hypotube and hydrophilic coated distal polymer shaft. The distal portion of the catheter has two platinum iridium marker bands for radiopacity. Promus ELITE has a polymer inner component and polymer balloon.

Contains cobalt: The stainless steel hypotube is a metal alloy that contains cobalt (CAS No. 7440-48-4; EC No. 231-158-0, which is defined as a 1B carcinogen and reproductive toxicant according to the European Commission in a concentration above 0.1% weight by weight). Current scientific evidence supports that metal alloys containing cobalt used in medical devices do not cause an increased risk of cancer or adverse reproductive effects.

Instructions for Use (IFU):

CONTRAINDICATIONS

Use of the Promus ELITE Stent System is contraindicated in patients with the following:

- Known hypersensitivity to platinum, the platinum chromium alloy, or similar alloy types such as stainless steel.
- Known hypersensitivity or contraindication to everolimus or structurally related compounds.
- Known hypersensitivity to the polymer or its individual components.
- Known severe reaction to contrast agents that cannot be adequately pre-medicated prior to the Promus ELITE Stent placement procedure.

Coronary artery stenting is contraindicated for use in the following:

- Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or delivery device.

Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for use only in countries with applicable health authority product registrations.

For more information, contact your local sales representative.

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